

REMARKS

The foregoing amendments and the following remarks are submitted for entry and consideration in response to the communication dated January 28, 2008.

Status of the Claims

Claims 14-17 and 33-36 are pending in the application. Claim 36 has been canceled, without prejudice. Claims 14, 15, 16, 33, 34, and 35 have been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Therefore, by this amendment claims 14-17 and 33-55 are now pending and presented. With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications. No new matter is added by the amendment of the claims or in the newly presented claims.

Support for the amended claims can be found generally through Applicants' Specification. In particular, Applicants point to the Specification, including at page 3, lines 9-11, page 8, lines 18-20, page 36, lines 7-11 and page 54, line 30 through page 55, line 2, for support for the specific amended claim language.

Claim Rejections - 35 U.S.C. 112 – New Matter

Claims 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is set out as a new matter rejection, the Examiner maintaining that the recitation "and do not give rise to functional gametes" is considered new matter because there is no description in the Specification for a pluripotent embryonic-like stem cell that does not give rise to functional gametes. In conjunction with this rejection, to the extent that the Examiner asserts that claimed compositions and/or methods are not described in the instant disclosure, the Examiner rejects claims 14-17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the Specification as to

enable the skilled artisan to make and/or use the invention. The Examiner asserts that Applicants provided citations do not specifically provide support for these embodiments. Applicants respectfully submit that claims 14-17, particularly as presented and amended, meet the written description requirement and are thereby fully enabled by the specification. Applicants point out that the language of independent claims 14-16 has above been amended, without prejudice to further or future prosecution, so as to more particularly set out and claim the instant stem cells. Applicants assert that the language of claims 14-17, including as above amended, is fully supported, described, and enabled in and by the specification. In particular, Applicants point to the Specification, including at page 3, lines 9-11, page 8, lines 18-20, page 36, lines 7-11 and page 54, line 30 through page 55, line 2, for support for the specific amended claim language. Applicants respectfully submit that the claims, particularly claims 14-17 as presented and amended, meet the written description requirement and are fully enabled by the specification.

Claim Rejections - 35 U.S.C. 112 – Enablement

Claims 14-17 and newly added claims 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner argues that the claims broadly encompass isolated pluripotent embryonic-like stem cells from any species, isolated from any non-embryonic or postnatal animal cell or tissue, and asserts that the specification provides no specific guidance with regard to the cells and specific phenotypes such that one of skill in the art could, given the teachings of the specification, make and use these cells in any of the contemplated uses. Applicants respectfully disagree and submit that claims 14-17 and 33-35, including as above amended, are fully enabled. Applicants point out that claim 36 has above been canceled. The Examiner remarks that the cells that have been described in the instant specification fail to have properties that would render them embryonic-like stem cells, as required by the claims. He further remarks that Applicants' cells are no longer "embryonic-like stem cells" because they express markers and have phenotypes and characteristics that fail to establish that they are like an ES cell. Overall, he says, the specification provides various

markers that are expressed by the claimed cells, but does not provide sufficient guidance to show that these cells are “embryonic-like pluripotent stem cells”, because these markers do not specifically define and identify an ES cell. Applicants acknowledge and appreciate that the Examiner understands and recognizes that Applicants’ instant stem cells are absolutely distinct from prior art ES cells. The full extent of any of the instant stem cells’ embryonic-like features reside in their capability to differentiate to cells of each an any of endodermal, ectodermal and mesodermal lineages – it is this feature that led to naming or designating them as embryonic-like. Applicants, however, again continue to assert that the instant stem cells are new, novel, and unique from any stem cells, embryonic-like (ES) or otherwise, in the prior art. Applicants respectfully submit that the stem cells of Applicants are enabled by the specification and, particularly, as claimed in claims 14-17 and 33-35, including as above amended. In the interest of facilitating prosecution and without prejudice to any further or continued prosecution, Applicants have above amended the claims, including to eliminate the descriptive term “embryonic-like” from the claim. Applicants submit that, particularly to the extent that this term was merely a name and descriptive, this amendment does not serve to limit the claims by amendment. Applicants argue that the instant claims, including as above amended, provide identification and characterization of the claimed cells to establish and uniquely identify the instant stem cells. The claims set out characteristics and tests recognized by and available to the skilled artisan to make, test, establish, verify, and uniquely identify the instant stem cells.

Claim Rejections - 35 U.S.C. 112 – Written Description

The Examiner rejects claims 14-17 and 33-36 as failing to comply with the written description requirement. The Examiner asserts that the specification fails to provide sufficient, identifying characteristics of the claimed cells such that one of skill in the art would recognize that Applicants had possession of the claimed cells. Applicants respectfully traverse this rejection. Applicants point out that claim 36 has above been canceled. Applicants argue that the instant claims, particularly and including as above amended, provide identification and

characterization of the claimed cells to establish and uniquely identify the instant stem cells. The claims set out characteristics and tests recognized by and available to the skilled artisan to establish, verify, and uniquely identify the instant stem cells. Claims 14-17 and 33-35, including as above amended, comply with the written description requirement.

In view of the foregoing remarks and the above amendments, Applicants submit that the Examiner's 112, first paragraph, rejections, including new matter, enablement and written description rejections, are obviated and should be withdrawn.

Claim Rejections – 35 USC § 112, Second Paragraph

Claims 14-17 are rejected under 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner asserts that claims 14 and 15 are unclear in that they all relate to pluripotent embryonic-stem cells, derived from non-embryonic or postnatal animal cells or tissue. The Examiner asserts that it is unclear how the language "not derived from embryonic tissue" and "not totipotent" claim further limits this recitation. Applicants respectfully disagree, however, in the interest of facilitating prosecution and enhancing clarity, Applicants have above amended each of claims 14, 15, and 16 to delete unclear language and provide further language to particularly and clearly characterize and describe the claimed stem cells. Applicants respectfully submit that the language of the claims is clear and definite and request that the claim rejections under 35 U.S.C. §112, second paragraph, be withdrawn.

The §103 Rejections

The Examiner has maintained his rejection of claims 14-17 as unpatentable under 35 U.S.C. 103(a) over Shablott [PNAS 95:13726-13731 (1998)] when taken with Sambrook et al [Molecular Cloning, Book 3, 1989]. The Examiner cites Shablott et al. as teaching the generation of human pluripotent stem cells from gonadal ridges and mesenteries containing

primordial germ cells (PGCs) and teaching that embryoid bodies collected from these cultures revealed a wide variety of differentiated cell types, including derivatives of all three embryonic germ layers. The Examiner notes that the claims are directed to pluripotent cells derived from non-embryonic tissues or postnatal animal cells or tissue, and as such, the fetal tissue described by Shamblott et al teach this requirement. Further, the Examiner asserts that the claims do not provide any requisite characteristics of the claimed stem cells such that they would be distinguished from the cells taught by Shamblott. Applicants again assert that the claimed pluripotent stem cells are distinguished from the Shamblott PGC cells and are not rendered obvious by the combination of the Shamblott and Sambrook references. The Examiner seems to specifically be requesting a specific cell marker for distinction. Applicants respectfully traverse this request and presumed requirement. Frankly, cells have been and can be distinguished from one another by any of various characters, activities and functions. While a cell marker is one among many, it is not the only characteristic possible or suitable for distinction. The stem cells of the present invention are distinct from and further are not obvious from the cells of Shamblott *et al.* Embryonic stem cells (ES) and embryonic germ cells (EG) cells have a disorganized and heterogeneous nature of development in culture, forming embryoid bodies (EB) which are aggregates of cells, and when these cells are implanted into animals or presented subcutaneously they form teratomas or tumors containing derivatives of all three germ layers (see Specification, including at page 4, lines 15-21). Applicants pluripotent stem cells do not form tumors in an animal, as recited in the above claims. Further, this disorganized and heterogeneous nature of ES and EG cells makes them impossible to manipulate to commit to a specified lineage or to multiple separate lineages, and thereby they are not capable of incorporation into the existing tissue because of their heterogenous, unpredictable, and teratogenic character. Applicants pluripotent stem cells do not have these characteristics and can remain quiescent, lineage uncommitted in the absence of a general or specific lineage commitment agent, capable of self-regeneration prior to commitment to any particular tissue lineage (ectodermal, endodermal, or mesodermal) and then further proliferation once committed, can be manipulated to commit to multiple separate tissue lineages, and are capable of incorporation into the existing tissue, as

recited in the above claims as amended. The Sambrook reference, teaching only methods of transfecting mammalian cells with a gene of interest, does not make Applicants pluripotent stem cells obvious when combined with Shamblott. Shamblott's PGCs are absolutely distinct and do not anticipate, or make obvious, Applicant's pluripotent stem cells. The addition of or combination of Sambrook to Shamblott's cells does not serve to make Applicant's cells or method of isolating them obvious.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's 103 rejections are obviated and should be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Should the Examiner feel that further issues remain upon a review of this Response, he is invited to call the undersigned at the number listed below to effect their resolution. Early and favorable action on the claims is earnestly solicited.

No additional fees are believed to be necessitated by this response, however, in the event the U.S. Patent and Trademark office determines that claim fees, a further extension and/or other relief is required, applicant petitions for any required relief including extensions of time and claim fees and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 11-1053** referencing Docket no. 1304-1-019CIP.

Respectfully submitted,

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